



# U.S. Environmental Protection Agency

Registration and  
Re-evaluation of Pyrethroids,  
Pyrethrins, and Synergist (PPS)  
Chemicals



# Agenda

- Discussion of Registration/Re-evaluation Vehicles (reregistration and registration review)
- Registration/Re-evaluation of PPS Chemicals
  - What was done in Reregistration
  - What is planned for Registration Review
- Questions

# Pesticide Registration

- EPA regulates pesticides under the statutory authority of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
- A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs.

# Pesticide Registration

- EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices.
- Under FIFRA, EPA evaluates the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment and non-target species.
- EPA has separate review processes for three categories of pesticides: antimicrobials, biopesticides, and conventionals.

# Registered Synthetic Pyrethroids

Chemical Name	Year Registered	Chemical Name	Year Registered
Tetramethrin	1968	Fenpropathrin	1987
Allethrin Stereoisomers	1969	Lambda-Cyhalothrin	1988
Sumithrin	1970	Tefluthrin	1989
Resmethrin	1973	Cyphenothrin	1991
Permethrin	1979	Zeta-Cypermethrin	1992
Fenvalerate	1979	Prallethrin	1994
Fluvalinate	1980	Deltamethrin	1994
Cypermethrin	1983	Beta-Cyfluthrin	1995
Bifenthrin	1985	Imiprothrin	1998
Tralomethrin	1985	1RS, cis-Permethrin	2000
Esfenvalerate	1986	Gamma Cyhalothrin	2004
Cyfluthrin	1986		

# Registered Pyrethrins & Synergists

Chemical Name	Year Registered
Pyrethrins	1948
Pyrethrum	1991
Pyrethrum powder other than pyrethrins	2001
PBO	1948
MGK-264	1950



# Pesticide Re-evaluation – Reregistration

- EPA is reviewing older pesticides (registered prior to November 1984) to ensure that they meet current scientific and regulatory standards.
- This process considers the human health and ecological effects of pesticides and results in actions to reduce risks that are of concern.
- EPA also reassessed tolerances (pesticide residue limits in food) to ensure that they met the safety standard established by the Food Quality Protection Act (FQPA) of 1996. Tolerance reassessment was completed for all applicable PPS chemicals in August, 2006.

# Pesticide Re-evaluation – Reregistration

**Per FQPA, EPA considered and implemented a new safety standard** – reasonable certainty of no harm – that applied to all pesticides used on food commodities. Under this standard, EPA was to:

- **Reassess all existing tolerances** within 10 years. Reassess all other non-food pesticides registered prior to 1984 by 2008.
- Give special consideration to **risks to infants and children** when reassessing tolerances
- Assess "**aggregate risk**" from exposure to a pesticide from multiple sources when assessing tolerances
- Assess "**cumulative exposure**" to pesticides that have common mechanisms of toxicity



# Pesticide Re-evaluation – Reregistration

Chemical Name	Reregistration Eligibility Decision (RED)
Fenvalerate	2003 (voluntarily canceled)
Fluvalinate	2005
Resmethrin	2006
Permethrin	2006
Cypermethrin	2006
Pyrethrins	2006
PBO	2006
MGK-264	2006
Allethrin Stereoisomers	Scheduled 2007
Tetramethrin	Scheduled 2008
Sumithrin	Scheduled 2008



# PPS Chemicals in Reregistration

Each PPS chemical was assessed individually, and appropriate risk mitigation was developed based on the individual chemical's risk picture.

# Comments received by CA Stakeholders

- Concern for the increased use of PPS chemicals, and potential environmental impacts, such as:
  - an accumulation of PPS chemicals in the sediments of both residential and agricultural water bodies
  - toxic effects to aquatic organisms, especially sediment organisms
  - possible resistance of public health pests
  - increase of PPS chemicals in Publicly Owned Wastewater Treatment facilities; and discharge into effluent water.
- The comments were supported by recent monitoring data (D. Weston), which indicate that pyrethroids are accumulating in the sediment of the residential and agricultural water bodies sampled in California.

# Risk Reduction Options Utilized in PPS REDs

- Delete uses and application methods (agricultural, industrial and institutional, and residential)
- Limit amount, timing, frequency of use
- Restrict use to certified applicators
- Add Personal Protective Equipment (PPE) and other user safety requirements
- Require special packaging, engineering controls
- Extend Restricted Entry Intervals (REIs)
- Strengthen ecological safeguards and environmentally-protective product labeling (i.e. buffer zones, vegetative filter strips, spray drift language)
- Amended public health mosquito adulticide labels to be consistent with PR-2005-1.

# Limitations in PPS REDs

- No urban/residential model available to assess potential ecological risks from residential uses.
- Could not assess (or compare) ecological impacts from PPS chemicals as a group because a large majority were registered after 1984, and therefore, were not subject to reregistration.
- It is unknown if pyrethroids share a common mode of action. A common mode of action determination is expected to be made by 2008.
- No endangered species assessments.



# Future Commitments in PPS REDs

Although the Agency was not able to assess the ecological and human health effects of the PPS chemicals as a group during reregistration, the Agency has committed to assess the pyrethroids, pyrethrins, and synergists as a group during **registration review**.



# Registration Review

- New FIFRA provision requires periodic review of each pesticide's registration
- Covers **all** pesticides
- Goal is 15-year review cycle
- Flexible, transparent, open process, which includes public participation
- Ensures risk assessments and regulatory decisions consistent with the always evolving state of the science.

# New Decision Paradigm

- What has changed since the pesticide's last assessment?
- How significant is this change?
- Do we need new information?
- Is the regulatory position likely to change as a result of the new information?





# Beginning of Registration Review Process

## EPA

- Assembles background information (including completed risk assessments), determines data gaps, prepares a preliminary work plan for case, and places available information in the public docket for comment
- Reviews public comments and additional information received
- Determines whether new risk assessments and/or additional data are needed and develops a final work plan

# Completion of Registration Review Process

If needed, EPA

- Issues a DCI, receives and reviews data
- Completes
  - ☐ any new risk assessments
  - ☐ a new risk management decision
- Publishes the decision for comment
- Implements the decision



# Public Participation During Registration Review

- Public comment invited from all interested parties throughout all stages of Registration Review:
  - ☐ Initial docket openings
  - ☐ Significant risk assessments
  - ☐ All proposed decisions

# PPS Registration Review Schedule

Year Docket Opens		
2010	2011	2012
Allethrins Stereoisomers	Fenvalerate	Tefluthrin
Bifenthrin	Fluvalinate	Prallethrin
Beta-Cyfluthrin	Lambda-Cyhalothrin	Resmethrin
Cyfluthrin	Gamma Cyhalothrin	Sumithrin
Esfenvalerate	Imiprothrin	MGK-264
Cyphenothrin	Permethrin	Pyrethrum
Deltamethrin	PBO	Pyrethrins
1RS, cis-Permethrin		Pyrethrum powder other than pyrethrins
Fenpropathrin		
Tralomethrin		Tetramethrin
		Cypermethrin
		Zeta-Cypermethrin

# Ongoing Preparation for PPS Registration Review

- Implement PPS RED mitigation measures and modify labels appropriately.
- Determine whether the pyrethroids share a common mode of action.
- Coordinate and share data with the California Department of Pesticide Regulation (CDPR).
- Revise spray drift language for pyrethroid agricultural labels.
- Identify a model and appropriate scenarios for use in urban run-off modeling.
- Compile detailed use and usage information about the PPS chemicals, both agricultural and residential uses.
- Identification of data needs and possible group data call in.

# OPP Information

- **EPA Office of Pesticide Programs**

[www.epa.gov/pesticides/](http://www.epa.gov/pesticides/)

- **Pesticide Reregistration**

[www.epa.gov/pesticides/reregistration/](http://www.epa.gov/pesticides/reregistration/)

- **REDs/TREDsstatus & information:**

[www.epa.gov/pesticides/reregistration/status.htm](http://www.epa.gov/pesticides/reregistration/status.htm)

- **Registration Review**

[www.epa.gov/oppsrrd1/registration\\_review/](http://www.epa.gov/oppsrrd1/registration_review/)

- **Draft registration review schedule**

[http://www.epa.gov/oppsrrd1/registration\\_review/explanation.htm](http://www.epa.gov/oppsrrd1/registration_review/explanation.htm)



# Thank You

## Questions?